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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,604

08/19/2003

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T9105.C

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20450

7590

06/12/2008

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EXAMINER

WEIER, ANTHONY J

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

06/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/644,604	Applicant(s) WALSH ET AL.	
	Examiner Anthony Weier	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 13-26, 56-61, 68-82 and 109-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-26, 56-61, 68-82, and 109-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Finality

1. Due to the recent discovery of additional pertinent references and inadvertently overlooked rejection under 35 USC 112, the finality of the last Office Action has been withdrawn.

Election/Restrictions

2. This application contains claims drawn to an invention nonelected with traverse in the paper filed 3/3/06.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6, 13-26, 56-61, 68-82, and 109-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 56, and 109, it is not clear if the percentages cited therein refer to the final textured whey protein product or whether they refer to the composition prepared prior to the thermoplastic extrusion. The instant claims call for a product "comprising a thermoplastic extrusion product *of a composition* comprising about 1-80%....protein..." (see claim 1).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 13-16, 56-59, 68-71, 82, and 109-113 are rejected under 35

U.S.C. 102(b) as being anticipated by Morimoto et al.

Morimoto et al discloses a texturized protein product comprising a thermoplastic extruded product of a mixture comprising a dried heat-coagulable protein (e.g. milk whey, inherently food-grade and undenatured, at least until heat treated) and starch (e.g. cornstarch). It should be noted that the mixture, prior to the addition of water (see step (c) in claim 1) may consist of, as one alternative, only said heat coagulable protein (e.g. whey protein, see 100% reference in step (a) of claim 1) and as high as 30% starch and a "minor amount" of a metal sulfate (described elsewhere in the specification as being less than 2.5%, e.g. col. 3). Taking into account the amount of starch and metal sulfate (roughly 30-32.5%), the amount of said 100% heat coagulable protein of the dry mixture of step (c) would be 70 to 67.5% which falls within the range called for in the instant claims. Morimoto et al further discloses the presence of, for example, 60% protein which falls within the range set forth in claim 2. It should be noted that Morimoto et al further discloses the presence of nonheat-coagulable animal proteins such as caseinate.

7. Claims 109 and 116-118 are rejected under 35 U.S.C. 102(b) as being anticipated by Yackel, Jr. et al.

Yackel, Jr. et al discloses a texturized protein product comprising a thermoplastic extruded product of a mixture comprising at least 40% protein (e.g. milk whey; col. 2, lines 33-54) and calcium chloride (e.g. col. 3, lines 7-25).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5, 6, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al alone or in view of de Ruyter.

The claims further call for the presence of plant proteins and, in particular, wheat protein. Morimoto et al discloses the use of such plant proteins (col. 3) but as alternatives to milk whey protein. In other words, Morimoto et al does not disclose the combination of such plant proteins with milk whey protein. However, since each protein component serves the same purpose, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed same together to serve the same purpose. It is obvious to combine two component each of which is taught by the prior art for the same purpose to form a third composition for the same purpose. In re Kerkhoven 205 USPQ 1069. In the alternative, de Ruyter teaches the preparation of an extruded texturized protein product which employs both heat-coagulable animal and plant proteins. It would have been further obvious to have employed both plant and animal proteins as a matter of preference due, for example, to

the particular amount of protein available, cost involved, or the particular nutritional composition desired in the final product.

10. Claims 23-26 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al.

The instant claims call for the inclusion of sweet whey. Although Morimoto et al discloses the use of whey in general, same is a notoriously well known type of whey, and it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed sweet whey as a matter of preference in view of, for example, cost and availability.

The claims further call for the whey protein to be in concentrate or isolate form. Morimoto et al discloses the use of whey protein in general but provides no specifics as to the degree of purity of same. Such forms for protein are notoriously well known, and it would have been further obvious to have incorporated either form as a matter of preference depending on, for example, the particular protein form that is available.

11. Claims 1-6, 13-16, 23-26, 56-61, 68-71, 77-82, 109-113, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldbrugge et al.

Feldbrugge et al discloses a texturized protein material produced by thermoplastic extrusion¹ wherein same contains whey which may be available in either concentrate or isolate form (e.g. col. 4, lines 3-21). It should be noted that Feldbrugge et al further discloses that a certain amount of the protein employed must be undenatured (see col. 3, line 64). Feldbrugge also discloses the use of wheat protein

but is silent regarding the combination of, for example, wheat and whey proteins. However, since each protein component serves the same purpose, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed same together to serve the same purpose. It is obvious to combine two component each of which is taught by the prior art for the same purpose to form a third composition for the same purpose. In re Kerkhoven 205 USPQ 1069.

Feldbrugge et al also discloses the inclusion of starch ingredients (col. 4, line 65) but is silent regarding the more specific use of cornstarch as claimed. However, cornstarch is notoriously well known, and, absent a showing of unexpected results, it would have been further obvious to have included same as a matter of preference depending on, for example, availability or cost.

The claims further call for particular amounts of the protein and polysaccharide components of the product. However, such determination would have been well within the purview of one having ordinary skill in the art, and it would have been obvious for said one at the time of the invention to have arrived at such amounts as a matter of preference depending on, for example, cost or availability of such ingredients.

The instant claims call for the inclusion of sweet whey. Although Feldbrugge et al discloses the use of whey in general, same is a notoriously well known type of whey, and it would have been further obvious to have employed sweet whey as a matter of preference in view of, for example, cost and availability.

¹ Morimoto et al refers to Feldbrugge et al for its thermoplastic extrusion process (see col. 1, lines 31-33).

12. Claims 17, 18, 72, 73, 114, and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al or Feldbrugge et al taken together with Villagran et al.

The claims further call for the inclusion of more specific polysaccharides not taught by Feldbrugge et al or Morimoto et al (e.g. pectin). However, it is known to employ such ingredients in extruded food products as taught, for example, by Villagran et al which teaches the inclusion of a variety of polysaccharide materials (carboxymethylcellulose, maltodextrin, pectin, etc.). It would have been obvious to one having ordinary skill in the art at the time of the invention to have employed such ingredients in the product of either one of Morimoto et al or Feldbrugge et al wherein same would possess, for example, less gumminess (see Abstract).

13. Claims 19-21, 74-76, and 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al or Feldbrugge et al taken together with JP 58-28235, Yackel, Jr. et al, or Ohyabu et al.

The claims further call for the inclusion of a calcium source (e.g. calcium chloride). However, it is well known to employ calcium sources such as calcium chloride in extruded proteinaceous food products as taught, for example, by JP 58-28235. Yackel, Jr. et al teaches the use of same to toughen the texture of the extrudate, thus suggesting the use of same to provide a certain desired texture (col. 3). Ohyabu et al teaches the inclusion of calcium chloride in protein extrudates as a dehydrating agent (e.g. col. 4). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included calcium chloride in the product of either one of

Feldbrugge et al or Morimoto et al for the reasons employed in JP 58-28235, Ohyabu et al, or Yackel, Jr. et al and/or, simply, for calcium fortification of a food product.

14. Claims 22, 77, 82, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al or Feldbrugge et al taken together with Ohyabu et al.

The claims further call for the inclusion of a pH adjusting agent. Ohyabu et al teaches the treatment of protein in an acid bath to stabilize product as well as improve the heat resistance and tensile elongation of same (e.g. col. 1, line 57 - col. 2, line 15). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included such treatment to provide the benefits recited in Ohyabu et al.

It should be noted that if it is shown that Morimoto et al and Feldbrugge et al do not provide a whey protein that is undenatured, same would be avoided due to the acid treatment as taught in Ohyabu which imparts heat resistance to the material.

15. Claims 114 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yackel, Jr. et al taken together with Villagran et al.

The claims further call for the inclusion of specific polysaccharides. However, it is known to employ such ingredients in extruded food products as taught, for example, by Villagran et al which teaches the inclusion of a variety of polysaccharide materials (carboxymethylcellulose, maltodextrin, pectin, etc.). It would have been obvious to one having ordinary skill in the art at the time of the invention to have employed such ingredients in the product of Yackel, Jr. et al wherein same would possess, for example, less gumminess (see Abstract).

16. Claim 119 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yackel, Jr. et al taken together with Ohyabu et al.

The claims further call for the inclusion of a pH adjusting agent. Ohyabu et al teaches the treatment of protein in an acid bath to stabilize product as well as improve the heat resistance and tensile elongation of same (e.g. col. 1, line 57 - col. 2, line 15). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included such treatment to provide the benefits recited in Ohyabu et al.

Response to Arguments

17. Applicant's arguments filed in the Brief filed 3/14/08 have been fully considered but they are not persuasive and have been addressed in the rejections above or the "Response to Arguments" section of the Final Office Action (mailed 12/13/06).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anthony Weier
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Art Unit 1761

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Anthony Weier
June 4, 2008